

**REMARKS**

**Election Of Invention And Sub Invention**

In the Office Action of June 16, 2009 (hereafter “Office Action”), the Examiner restricted the pending claims 1-30 into three (3) groups (“Inventions”):

Group I, including claims 1-10, drawn to an apparatus;

Group II, including claims 11-13 and 30, drawn to a composition; and

Group III, including claims 14-29, drawn to a method of using the composition.

The Examiner requested Applicants to elect a single invention of Group I, Group II, or Group III.

Applicants do not believe that this restriction requirement is proper.

More specifically, claims of Group I include the limitation “a device for introducing the capreomycin into *gases* for inhalation;” claims of Group II are drawn to a formulation suitable for *aerosol* administration; and claims of Group III include the limitations of introducing capreomycin into *gases* to be inhaled, administering an *aerosolized* capreomycin and use of capreomycin for *aerosolized* administration.

As the Examiner appreciated, the special technical feature of Applicants’ invention is an *aerosolized* formulation of capreomycin, uses thereof and systems comprising it. On page 5, lines 6-8, of Applicants’ application as filed, Applicants state that capreomycin was discovered in the 1960s and “has always been administered by intramuscular injection or intravenous administration” – i.e., in solid or liquid form. And further, on page 6, lines 9-11: “Surprisingly, it has now been discovered that capreomycin is active against tuberculosis when administered by inhalation into the lungs. This could not have been predicted.”

In the Office Action, explaining why the subject matters of Groups I-III allegedly do not relate to a single general inventive concept under PCT Rule 13.1, the Examiner stated that

“they lack the same or corresponding special technical features for the following reasons: a formulation of capreomycin for *aerosol* (intranasal) administration is known in the art (US 5,807,830. column 14, lines 1-8 and column 22, lines 15 and 63) and thus there is no special technical feature.” (emphasis added)

Reviewing the passages of US 5,807,830 (“’830 patent”) as cited by the Examiner, Applicants were not able to identify a disclosure that would indicate to one of skill in the art that the ‘830 patent discloses an *aerosol* formulation of capreomycin. At the beginning Applicants note that capreomycin seemingly is only listed once in the ‘830 patent in column 22, line 63 as part of a long list of an anti-infective agent (as indicated by the Examiner). Column 14, lines 1-8, the ‘830 patent discloses an intramuscular dose and an intranasal dose of a R’-Glu-Trp-R” pharmaceutical preparation. One of skill in the art will appreciate that this is a different pharmaceutical preparation or formulation than the capreomycin formulations and compositions of Applicants’ invention. Further, the ‘830 patent discloses on column 54, lines 45 to 47, that the L-Glu-L-Trp was introduced by intranasal instillation of 8-15 *drops* of a 0.001% solution. Thus, seemingly the pharmaceutical compositions described in the ‘830 patent are not *aerosol* formulations as in Applicants’ invention.

Accordingly, Applicants submit that the pending claims 1-30 share a specific technical feature, and thus, relate to a single general inventive concept under PCT Rule 13.1, namely an *aerosolized* formulation of capreomycin, uses thereof and systems comprising it, which are not disclosed in the ‘830 patent. As such, this technical feature is novel in view of the disclosure of the ‘830 patent. Thus, claims 1-30 should be grouped into a single group.

In the event the Examiner does not group pending claims 1-30 into a single group, without acquiescing to the propriety of the Examiner’s determination of three inventions (Groups I-III), but rather in the interest of furthering prosecution of this application, Applicants herewith elect with traverse:

Group III, including claims 14-29, drawn to a method of using the composition.

In view of the Examiner's comments and arguments presented herein, Applicants respectfully request reconsideration of the restriction requirement and grouping of claims 1-30 into a single group.

Upon entering this amendment, and not reconsidering the restriction requirement, claims 14-29 are claims encompassing the elected invention.

**Status of the Claims**

Claims 1-30 are pending.

**Amendments To The Claims**

Applicants have amended claims 1-10, 12-27, and 29 for clarity, specifically replacing the "A" at the beginning of dependent claims with "The" and replacing the phrase "said" with "the."

No new matter has been introduced by way of these amendments.

**CONCLUSION**

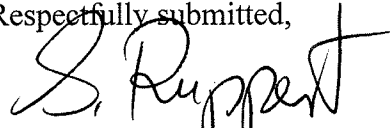
Applicants believe that no additional fee is required. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Appl. No.: 10/527,557  
Amdt. dated December 16, 2009  
Response to Restriction Requirement & Preliminary  
Amendment

PATENT

If the Examiner believes a telephonic conference would expedite prosecution of this application, please telephone the undersigned at (415) 576-0200.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "S. Ruppert", written over the typed name.

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